

PSJ15 Exh 86

Message

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**From:** Tetzlaff, Gail S [/O=MKGLOBAL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=GAIL.TETZLAFF]  
**Sent:** 8/28/2014 7:13:19 PM  
**To:** Buist, Jennifer M [/O=MKGLOBAL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Jennifer.Buist]; New, Bonnie I [/O=MKGLOBAL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Bonnie.New]  
**CC:** Spaulding, Eileen L. [/O=MKGLOBAL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Eileen.Spaulding]; Williams, Jane L [/O=MKGLOBAL/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Jane.Williams]  
**Subject:** RE: VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Approved.

Gail Tetzlaff | Director of Government Reporting Compliance  
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**From:** Buist, Jennifer M  
**Sent:** Thursday, August 28, 2014 2:12 PM  
**To:** New, Bonnie I  
**Cc:** Tetzlaff, Gail S; Spaulding, Eileen L.; Williams, Jane L  
**Subject:** RE: VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Gail – I recommend release.

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**From:** New, Bonnie I  
**Sent:** Thursday, August 28, 2014 2:07 PM  
**To:** Buist, Jennifer M  
**Cc:** Tetzlaff, Gail S; Spaulding, Eileen L.; Williams, Jane L  
**Subject:** RE: VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Jen,

He did not say. I believe that was his point when told me they have a SOM program monitoring customers.

Thank you,  
Bonnie

Bonnie New | National Account Director  
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**From:** Buist, Jennifer M  
**Sent:** Thursday, August 28, 2014 1:59 PM  
**To:** New, Bonnie I  
**Cc:** Tetzlaff, Gail S; Spaulding, Eileen L.; Williams, Jane L  
**Subject:** RE: VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Thanks Bonnie.

Is their increase in demand for one customer or is it spread across multiple customers?

I appreciate the other information; we are aware HDS is their parent.

Thank you,

Jen

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**From:** New, Bonnie I  
**Sent:** Thursday, August 28, 2014 1:46 PM  
**To:** Buist, Jennifer M  
**Cc:** Tetzlaff, Gail S; Spaulding, Eileen L.; Williams, Jane L  
**Subject:** RE: VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Jen,

They have had increased demand, just talked to him, I believe we need to increase their amount. Over the last four months they gone from 1, 11, 23, to 46 on these strengths.

They have a SOM program in place so they are monitoring it too. Just in case you don't know, they are owned by H.D. Smith.

Please let me know if you need anything else.

Thank you,  
Bonnie

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**From:** Buist, Jennifer M  
**Sent:** Thursday, August 28, 2014 11:23 AM  
**To:** New, Bonnie I

**Cc:** Tetzlaff, Gail S; Spaulding, Eileen L.; Williams, Jane L  
**Subject:** RE: VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Bonnie,

This order remains on hold. Can you provide an update please.

Thank you,

Jen

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**From:** Buist, Jennifer M  
**Sent:** Monday, August 25, 2014 7:51 AM  
**To:** New, Bonnie I  
**Cc:** Tetzlaff, Gail S; Spaulding, Eileen L.  
**Subject:** VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG

Bonnie,

We have VALLEY WHOLESALE order 70322319on U2 hold for FENTANYL LOZENGE 600MCG and 800MCG. Their quantity ordered exceeds any total quantity for customers within their segment for the last 18 months. Please see below for verbiage you can send to the customer if need be.

Please do not hesitate to contact me should you have further questions.

Thank you,

Jen

Order Number	Bill To Customer	Bill To Customer Name	Ship To Customer	Ship To Customer Name
70322319	50073897	VALLEY WHOLESALE DRUG CO INC, STOCKTON, CA	698900	VALLEY WHOLESALE DRUG CO INC, STOCKTON, CA
70322319	50073897	VALLEY WHOLESALE DRUG CO INC, STOCKTON, CA	698900	VALLEY WHOLESALE DRUG CO INC, STOCKTON, CA

Dear XXX,

As a manufacturer of controlled substances, Mallinckrodt is required by the Drug Enforcement Administration regulations to monitor orders of controlled substances as part of its Anti-Diversion Program.

Our Anti-Diversion Program has identified the order listed below for additional review. Please provide additional information about the circumstances that led to this order. For example, if you recently have experienced a significant increase in your customer base or if another manufacturer of this product is experiencing difficulty supplying this product, provide details about those circumstances.

Customer Order #	NDC	Item	Quantity
0453751	0406920630	FENTANYL LOZENGE 600MCG	10.000
0453751	0406920830	FENTANYL LOZENGE 800MCG	10.000

Jen Buist | Sr. Data Analyst, Controlled Substances Compliance  
Legal Department  
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